DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

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OFFICE OF RESEARCH AND DEVELOPMENT
PROGRAM ANNOUNCEMENT INVITING PROPOSALS FOR
CLINICAL RESEARCH CENTERS OF EXCELLENCE (CRCoE)

1. **Purpose.** The Veterans Health Administration's (VHA) Office of Research and Development (ORD) invites applications to establish Clinical Research Centers of Excellence (CRCoEs). CRCoEs are designed to advance VA's clinical research capacity[1] for integrating state-of-the-art science with clinical practice for our veterans. Initially, CRCoE awards are intended primarily to develop a national network of research facilities that is dedicated to training the next generation of leaders in clinical research. All CRCoEs will work together and serve as a national clinical research resource to help mentor and develop clinical researchers throughout the VA. Furthermore, CRCoEs will provide a national clinical research "consultation resource" to support VA investigator-initiated clinical research ideas. Once established, CRCoEs will also be responsible for developing and maintaining a clinical research portfolio in their chosen areas of excellence. Funding for this program will include salary support for junior faculty selected for training and up to $400,000 per year for establishing a core facility of methodologists to assist with clinical research design, conduct, and grant development. By placing a particular emphasis on training and mentoring clinical researchers and providing a mechanism for developing clinical research through VA, this CRCoE program aims to enhance VA's ability to provide the best health care possible for our veterans.

2. Background. Despite the historical investment by the NIH and VA in bench research, there is a general consensus among the scientific community that resulting discoveries are not being efficiently seized and converted into clinical practice that directly and positively impacts the health care of veterans and our nation (Sung et. al., 2003). At the same time, much of clinical

[1] **Clinical research** is defined in this announcement as patient-oriented investigations focusing on mechanisms of human disease, therapeutic interventions, clinical trials, and/or the development of new technologies, epidemiological and behavioral studies, and outcomes and health services research.

practice in the United States is not based on rigorous, state-of-the-art, evidence-based clinical research findings.

In order for Today's VA Research to Lead Tomorrow's Health Care, evidence-based clinical practice must be a major strategic priority for VA in the care of our veterans. ORD recognizes that the first step in achieving that goal requires growth in the number of clinicians who can effectively apply rigorous clinical research experimental methods to basic and early clinical scientific discoveries to achieve VA's promise of improved health care to our veterans.

In the last decade, there has been an increase in the number of academic generalists who have pursued careers in outcomes research. However, there remains a greater need for subspecialists with a solid foundation in key clinical research disciplines including statistics, epidemiology, psychometrics, and qualitative methods (Grunberg & Cefalu, 2003). By increasing VA training opportunities for clinician-investigators (the foundation that supports the quality of the VA health care system), greater capacity will exist for the progression of important bench research findings to early clinical trials and eventually large, "evidence-based" cooperative clinical trials.

3. Eligibility. Applications may be submitted by any VA facility. However, applicants must consider their ability to meet the following requirements:

a. The primary requisite of successful CRCoE applicants will be the ability to clearly document the available resource base for properly training and mentoring junior faculty in the fundamental principles on which evidence-based clinical research is grounded;

b. Applicants must indicate their ability to leverage local academic resources (e.g., existing K-type awards and/or local educational programs, including Masters of Public Health and Masters of Clinical Research programs) to provide Masters-level clinical research training for junior faculty. If possible, CRCoEs should integrate existing local Masters of Public Health or similar coursework into a structured CRCoE educational training program. Although not an absolute requirement, sites that have already demonstrated success in developing junior faculty and/or an ability to successfully obtain and develop career development awardees in clinical research disciplines will be considered favorably;

c. CRCoE awardees must indicate a willingness to participate in and contribute to a national integrated network of all CRCoEs. Participation will include attending a National Planning Meeting involving all CRCoEs in the first year of funding. At that meeting, CRCoE members will develop a training course that will be made available throughout VA (including web-based access) for anyone interested in receiving Masters-level training in statistics, epidemiology, study design, survey research, health economics, and related fields. The meeting also will address ORD's plans for enabling individuals to travel to and work part-time with their CRCoE mentors. Also to be developed at the meeting are methods for: assessing CRCoE performance; pairing mentors with mentees; enabling individuals to apply and be selected nationally; and determining how CRCoEs might receive additional funding based on increased demand;

d. CRCoEs are to be national leaders and resources for clinical research. Therefore, CRCoEs must develop and maintain a dynamic local clinical research portfolio supported by investigator-initiated funding. Additionally, CRCoEs must be committed to "serve" individual investigators as a methodological resource with funded clinical studies and/or individuals who are interested in developing a grant for investigating important clinical research questions.

4. Overview of CRCoE Structure and Responsibilities. This program announcement (PA) provides an opportunity to develop the capacity to guide the development of the next generation of clinical researchers. Individual awards will be up to a maximum of $400,000 per year in total costs for up to five years. The initial award is for the core facility and is to fund a minimum of two FTEE methodologists, an administrative manager (maximum 0.5 FTEE) to provide administrative support, and research facilities sufficient to meet the purposes of this CRCoE program.

The Principal Investigators (up to .25 FTEE) will serve as CRCoE Directors. The CRCoE Director will be responsible for coordinating all training and research activities and must articulate a strong commitment to mentoring and developing clinical research investigators. The CRCoE Director must be a senior individual who is at least a 5/8th FTEE VA employee with proven success in mentoring and developing young scholars or investigators in the scientific disciplines on which sound clinical research is based. In addition, the CRCoE Director must

coordinate a team of scientists with expertise and mentoring experience in the fundamental disciplines of clinical research (e.g., epidemiology, biostatstics, health economics, etc.) and clinicians to act as mentors across a wide variety of clinical subspecialties (e.g., cardiology, gastroenterology, surgery, psychiatry, etc.) at the applicant institution.

Once CRCoEs are established, they will also be provided support for two to three junior faculty awards per year for up to five years to support their clinical research career development. Junior faculty award recipients will be known as Clinical Scholars. Any individual Clinical Scholar can receive up to five years of funding, of which two years are to be dedicated to receiving Masters-level training and the subsequent three years to be devoted to establishing their independent scientific career. Individuals entering the program with a Masters in a related field (e.g., Masters of Public Health) will be limited to three years of funding. Applicants for Clinical Scholars will be individuals who have recently completed clinical residency or fellowship training who are commencing clinical and translational research careers in areas relevant to veterans' health issues. Applicants for Clinical Scholar positions must be within five years of their last clinical training. CRCoEs will select physicians for Clinical Scholars awards. Funding for selected individuals will be provided upon ORD's approval of the physician candidate. Therefore, Clinical Scholars will be chosen at the discretion of CRCoEs but in consultation with and with approval from ORD. ORD will also have pilot research funds available for supporting the initial research efforts of Clinical Scholars.

Once the CRCoEs are chosen, a National Planning Meeting of all CRCoEs will be convened to 1) develop a national training program (including a web-based program) through which anyone can obtain Masters-level training in the key disciplines of clinical research, 2) determine methods for assessing CRCoE performance, 3) determine processes for pairing mentors with Clinical Scholars, 4) determine whether or not travel for mentoring purposes will be necessary, 5) establish processes for individuals to apply and be selected nationally as Clinical Scholars, and 6) determine how CRCoEs might receive additional funding based on increased demand.

CRCoEs will be required to develop an integrated network to facilitate national outreach and a structured plan for training the next generation of skilled clinical researchers in VA. The network of CRCoEs will interface with independent VA investigators who seek scientific training and mentoring for research careers committed to enhancing veterans' health care.

CRCoEs will assist investigators in the development and/or conduct of research projects that address the immediate and long-term agendas of innovative clinical research. Such projects should be targeted toward advancing the understanding of the diagnosis, prevention, treatment, natural history, and rehabilitation of medical problems that impact veterans.

Finally, CRCoEs must advance a clinical research portfolio. The portfolio may be diverse, consistent with the individuals the CRCoE is training, or it may be focused in a more specific area. Although the portfolio may have a heavy emphasis in one area, CRCoEs will be required to demonstrate their ability do broad-based research training for individuals with diverse backgrounds (i.e., in different subspecialties such as medicine, surgery, psychiatry, rehabilitation, or other clinical disciplines). CRCoEs will utilize their core research staff of methodologists to assist in the design and conduct of scientifically sound, locally-based clinical research. CRCoEs are to consist of a multidisciplinary group of scientists and clinicians who can effectively collaborate in posing and examining important clinical research questions.

5. Phases of Center Development and Funding (phased-approach). In the first year, as the core facility is being established, ORD will support a core facility funded for up to a total of $400,000 dollars annually and consisting of the CRCoE Director (0.25 FTEE), a minimum of 2 FTEE research methodologists, an administrative manager (up to a maximum of 0.5 FTEE), and research facilities sufficient to meet the purposes of this CRCoE program. CRCoEs will coordinate with ORD in Year 1 to develop an on- and off-site training curriculum, national consultation, identification of local clinical scholars, and plans for integration with the national network of CRCoEs. These efforts will, in part, involve a National Planning Meeting to take place in this first year of funding.

Once the CRCoEs are designated, they may begin recruitment of junior faculty (i.e., Clinical Scholars) and request funding for their salaries. To ensure that the candidates to receive the Clinical Scholars funding are those needed to fulfill the clinical responsibilities of the hospital, the identification and recruitment of Clinical Scholars must be a joint effort between the CRCoE and local VAMC hospital administrators. ORD will fund 75 percent of a Clinical Scholar's salary, which will be protected time devoted to research efforts; local hospital administration will fund 25 percent of a Clinical Scholar's salary, which will be time spent performing local clinical activities. Funds will also available for supporting Clinical Scholars'

pilot projects. Additional salary support may also be provided to support the infrastructure and growth of CRCoE staff as demand on the CRCoE is increased by the national outreach effort.

6. Application Process

a. Letter of Intent. Applicants are required to submit a Letter of Intent (LOI) by October 21, 2003. For an example of the LOI format, see Attachment B. PIs will be notified if their applications do not fit the scope of this PA and/or are deemed to have low chance for success in a full application. The LOI should include a descriptive title of the proposed Program, the name, address, and telephone number of the Principal Investigator (i.e., proposed CRCoE Director), the identities of other key personnel and participating institutions, and the number and title of this PA.

b. Proposal Preparation and Submission. Applicants with an approved LOI will be invited to submit a full proposal for a CRCoE. All full proposals are due on February 2, 2004. Full proposals should clearly delineate how the proposed CRCoE will meet the objectives of this initiative and describe plans for CRCoE training, research, collaborations, and administration. Specific instructions for proposals are provided in Attachment C.

c. Review. A peer review committee will be appointed to conduct the review of complete applications. Reviews of applications will include determination of an applicant's abilities to meet the program's goals and whether existing resources are available to ensure the CRCoE's success in providing clinical research training to junior faculty in VA and serving as a clinical research resource.

Although ORD's financial plans provide support for this program, awards pursuant to this Program Announcement are contingent upon the availability of funds and the receipt of a sufficient number of applications of outstanding scientific and technical merit.

7. Inquiries. Application inquiries may be directed within the VA ORD Clinical Research Service to Grant Huang, M.P.H., Ph.D., by phone at (202) 254-0252 or by e-mail at grant.huang@hq.med.va.gov.

8. References

Grunberg SM, Cefalu WT. The integral role of clinical research in clinical care. New Engl J Med 2003; 348(14):1386-1388.

Sung NS et al. Central Challenges Facing the national clinical research enterprise. JAMA. 2003; 289(10):1305-6.

Nelda P. Wray, M.D., M.P.H.
Chief Research and Development Officer

Attachments

ATTACHMENT A

PROGRAM DESCRIPTION

Clinical Research Centers of Excellence (CRCoEs) are intended to support the training and development of junior faculty in the scientific disciplines that form the basis for clinical research and to facilitate clinical research and efforts for integrating current science with clinical practice for our veterans. In addition to having their own clinical research portfolio, CRCoEs will also be national resources for other investigators conducting clinical research or interested in doing such work. Applicants should consider their ability to meet program requirements before submitting a Letter of Intent and full proposal. Such consideration should pay particular attention to the multidisciplinary training and research goals of this program.

Training Focus. The primary focus of the training program will be on-site training of junior faculty. Additionally, all CRCoEs will unite to create a national outreach training program. While applicants are encouraged to develop innovative training strategies, training must include didactic coursework to ensure that Clinical Scholars develop Masters-level competencies in scientific disciplines that form the foundation of clinical research (e.g., epidemiology, statistics, behavioral sciences). Individual-level mentoring on learned principles and their application to clinical research also must be included as part of training efforts.

On-site Training. On-site training of junior faculty in the fundamental disciplines of clinical research is one of the major goals of the CRCoE initiative. CRCoE funds may be used to develop a structured clinical research training program for on-site training. Successful CRCoEs will capitalize on local training programs, including K-type awards and locally available Masters of Public Health and Masters of Clinical Research programs. CRCoE funds for methodologists should focus on using those individuals in their mentoring role and for grant development, not for providing didactic lectures. Involvement of Merit Review Entry Program (MREP) and Career Development trainees in CRCoE-related training is encouraged. Critical areas to be addressed in training should focus on strengthening foundations in research methodology and data analysis. Specific disciplines may include epidemiology, statistics, survey research, and health economics, among others. CRCoE staff should also design plans for one-on-one mentoring of junior faculty

(i.e., Clinical Scholars). Such mentorship may be provided by a team of senior investigators, including individuals with expertise in the appropriate clinical disciplines and training experience in the methodologic disciplines. Finally, CRCoEs must collaborate with local hospital administrators to assist with the recruitment of individuals in appropriate clinical areas as required by the patient care efforts of the hospital. Particular emphasis should be placed on recruiting minorities and other traditionally underrepresented groups in clinical research.

Off-site Training. All CRCoE applicants must state their willingness to participate in the design of a national outreach program to develop a national network for the training of the next generation of clinical researchers, including attendance at the National Planning Meeting. At that meeting, CRCoE members will develop a national training program that includes a web-based program for Masters-level education, determine methods for assessing CRCoE performance, determine processes for pairing mentors with mentees, determine whether or not travel will be necessary, establish processes for individuals to apply and be selected nationally, and determine how CRCoEs get additional funding based on increased demand. If a CRCoE applicant has had previous experience with these types of education efforts, that experience should be outlined in the application. The aim of these off-site training efforts is to enable those individuals seeking further training in clinical research but who do not reside in the CRCoE's immediate geographical area to be afforded such opportunities.

Research Focus. Each CRCoE applicant must describe the clinical areas in which they plan to develop their research portfolio. All CRCoEs will be required to conduct training across a spectrum of disciplines; therefore, the research focus may involve several different clinical areas. However, a site may have a more focused research effort as long as training can be conducted across the spectrum of disciplines.

Staffing and resources should enable multidisciplinary collaborations. Particular emphasis should be placed on the methodological expertise among CRCoE personnel. It is recognized that personnel and resources may be required to enable CRCoEs to achieve research objectives.

Director. The CRCoE Director is responsible for coordination of all training and research activities and must be at least a $5/8^{th}$ FTEE VA employee. The CRCoE Director also must be a

senior faculty member possessing the scientific expertise, leadership, mentorship and administrative skills required to achieve the program's multidisciplinary training and research aims. CRCoE Directors should be able to demonstrate a successful record of training in the disciplines in which clinical research is based and/or demonstrate a history of developing training programs.

Collaborators. In addition to the Director, the CRCoE application should be comprised of a team of collaborators/mentors who will contribute to and strengthen the CRCoE's training and clinical research capacities. The assembled staff should be qualified to execute a well-conceived plan that ensures and maintains collaborative efforts. Similar to the Director, collaborators should have established histories of training and research that indicate their ability to meet CRCoE's program goals. Applicants who can show prior expertise in the development of junior faculty in the disciplines on which good clinical science is based and success in career development programs (including VA Career Awards and NIH Career Awards) will be looked upon favorably.

Internal Steering Committee. Each CRCoE must establish an Internal Steering Committee to include the CRCoE Director, senior hospital administrators, and key selected CRCoE staff. Local experts may also be included, but the Internal Steering Committee should have no more than six members. The two major functions of the committee are to evaluate 1) applications from Clinical Scholar candidates and 2) the overall conduct of the program to ensure that it meets the program's goals. The Steering Committee also should coordinate initiation and termination of projects, direct allocation of resources, and provide oversight of the training program.

Institutional Environment: It is critical that each CRCoE site possess an environment that will contribute to its success. That environment includes having the appropriate mentors in the clinical disciplines and appropriate mentors in the scientific disciplines available to address a spectrum of clinical research. Successful CRCoE applicants are expected to have educational programs in place (NIH K-type awards, Masters of Public Health and Masters of Clinical Research programs). Applicant institutions should also facilitate multidisciplinary interaction among researchers. Other items that may help provide CRCoEs with a suitable environment for meeting program goals may vary. Examples include local educational institutions, regional

educational and/or scientific resources, already established training and/or research programs that have the flexibility to be integrated with the CRCoE, and technological capabilities and equipment.

Core Facility: This grant application is specifically to fund a core training facility around which the training efforts of the CRCoE will be built. Such a core facility will provide funding for skilled methodologists to complement the local educational programs and extend the capabilities of clinical mentors to promote the career development of Clinical Scholars. The core facility will include a minimum of two FTEE methodologists in the areas of biostatistics, epidemiology, health economics, clinical evaluation sciences, clinical trials, and/or the other disciplines on which sound clinical research is based. The award may also provide salary to support an administrative manager (up to 0.5 FTEE), up to 25 percent effort above and beyond any direct mentoring time for the Director, and provide funds for supplies, equipment, and appropriate costs of operation.

Allowable Costs:

1) Funding of the Program structure consists of the following:

a) **Administration**: It is expected that the Principal Investigator (CRCoE Director) will be a physician with training, prior experience, and clinical expertise for establishing a successful framework for building VA clinical research capacity. If VERA funds for MDs' time are distributed through ORD, that support will be provided above and beyond the $400,000 limit of this request. An administrative manager may be hired to assist with day-to-day activities. Limited administrative support (up to 0.5 FTEE) will be considered.

b) **Core Facility**: Budgets should include salaries and fringe benefits for a minimum of two FTEE methodologists, supplies, equipment purchase (including hardware and software), and maintenance, as needed. The sum of the budgets for the administrative component of the Administration and a Core facility may not exceed $100,000 (exclusive of VERA funds for MDs' time, if those funds are distributed through ORD).

ATTACHMENT B

LETTERS OF INTENT

1. A Letter of Intent (LOI) must be received in VACO Clinical Research & Development Service by **October 21, 2003,** for potential consideration of a full application on the **February 1, 2004,** deadline. Applications will not be reviewed without an approved LOI.

2. The format for the LOI is below:

a. Form 10-1313-13 should be used to provide the following information:
   i. VAMC;
   ii. Proposed Director of the CRCoE (Principal Investigator)
   iii. Application title;
   iv. Signatures of the Associate Chief of Staff, Research and Development (R&D) and VAMC Director.

b. A brief summary (1 page maximum) of the proposed CRCoE Director's mentoring experience and other qualifications that make him or her an appropriate candidate to be the CRCoE Director;

c. A list of all potential clinical mentors (mentors with expertise in one or more clinical areas), including name, academic title(s), clinical area(s) of expertise, current research funding, and experience as a clinical mentor;

d. A list of all potential mentors with substantial expertise in the scientific disciplines in which clinical research is based (may or may not be duplicative of some of individuals listed above; must have Masters-level or above training in statistics, epidemiology, study design, etc.), including name, academic title(s), area(s) of expertise, current research funding, and experience as a mentor;

e. A description of locally available academic resources (e.g., NIH K-type awards, Masters of Public Health or Masters of Clinical Research programs) that can be used to provide the coursework training for the Clinical Scholars program (1 page maximum).

c. A statement of willingness to participate in the design of a national training network.

3. Submit the original LOI and ten copies to:

If mailing through the U.S. Postal Service -

CRCoE LOI
Office of Research and Development (12)
Attn: Grant Huang, M.P.H., Ph.D.
U.S. Department of Veterans Affairs
810 Vermont Ave, NW
Washington, DC 20420

If using door-to-door courier services (e.g., FedEx) -

VHA Office of Research and Development (12)
Attn: Grant Huang, M.P.H., Ph.D.
1722 I Street, NW
Washington, DC 20006
(202) 254-0252

4. **Inquiries.** Inquiries to ORD may be directed to Grant Huang, M.P.H., Ph.D., at (202) 254-0252 or grant.huang@hq.med.va.gov.

ATTACHMENT C

INSTRUCTIONS FOR APPLICATIONS

1. Submit ten copies of the application, duplicated back-to-back on 8.5 x 11 inch white paper. Type the name of the CRCoE Director in the lower right portion of each numbered page. Limit the narrative (see Roman numerals I-X below) to twenty pages using letter-quality print using 12-point font and one-inch page margins.

2. The first two pages should be VA Form 10-1313-1 (Merit Review Application) and VA Form 10-1313-2 (Summary Description of Program), followed by a Table of Contents corresponding to the sections below.

3. I. Advantages of a CRCoE to the VA Medical Center (1 page maximum). CRCoEs are intended to provide an added dimension to a VAMC's clinical research activity. An explanation of how that expectation will be met is critical to the establishment of the CRCoE. Briefly summarize the special advantages of having this CRCoE at your VAMC and its anticipated impact on clinical research training, clinical research support and development, and the clinical care of patients in your VAMC or VA patients in general.

4. II. Budget and Staffing. Use VA Form 10-1313-3 and VA Form 10-1313-4 to summarize and justify the requested budget. Request only resources and facilities directly related to the CRCoE. List the staff members, academic title, VA title, VA employment status (8ths), and percent effort on the CRCoE as a direct cost. Use VA Form 10-1313-5 to provide a biographical sketch for the Principal Investigator (i.e., proposed CRCoE Director). More specific details on the background and qualifications of the proposed Director and CRCoE faculty mentors are to be provided in the sections discussed below. Biosketches of potential junior investigators that would be recruited may also be included in this section using VA Form 10-1313-5.

5. III. Training Program (2 pages maximum). Describe the proposed clinical research training program to be provided by the CRCoE. This description should include the course of study Clinical Scholars will take to meet a Masters-level competency in clinical research, clinical research training opportunities, and any professional development courses (e.g., grant writing,

ethics, protocol management, etc.) that are not already a part of the curriculum. This description also should specify how Clinical Scholars are to be evaluated during training and any expected degrees/outcomes indicating their competency to conduct sound clinical research. Partnerships with local institutions to meet training goals should be listed in this section. Further information that supports the training program description may be included in an appendix if necessary.

6. IV. Mentoring Program & CRCoE Faculty (4 pages maximum). CRCoEs are expected to provide both clinical and scientific mentoring of Clinical Scholars. Applicants should separately list the proposed mentors for each of these areas. For each of the proposed CRCoE clinical mentors, provide the following information: current title/position; a brief description of the mentor's own mentored experience/training (i.e., how was the mentor trained/mentored); area of clinical expertise; current area/focus of research; record of mentoring including number of students, the nature of mentoring relationships, and any publications/presentations with mentored students as co-authors; current professional status and key accomplishments of mentored students; and any unique contribution the mentor will provide to a multidisciplinary CRCoE clinical research program. Any teaching/mentoring honors or awards that have been received may also be listed in this section.

For each of the proposed CRCoE scientific mentors, provide the following information: current title/position; a brief description of the mentor's own mentored experience/training (i.e., how was the mentor trained/mentored); area of clinical expertise; current area/focus of research; record of mentoring including number of students, the nature of mentoring relationships, and any publications/presentations with mentored students as co-authors; current professional status and key accomplishments of mentored students; and any unique contribution the mentor will provide to a multidisciplinary CRCoE clinical research program. Any teaching/mentoring honors or awards that have been received may also be listed in this section.

7. V. Mentoring Plans (3 pages maximum). Describe the format and specific plans for mentoring Clinical Scholars. While CRCoEs are encouraged to develop innovative methods for mentoring Clinical Scholars in scientific and clinical disciplines, applicants should indicate the goals to be achieved through the CRCoE mentoring program. Major objectives and key milestones should be listed along with any efforts for ensuring that these objectives and milestones will be achieved. These plans should include a description for how the mentoring

process will help Clinical Scholars become independent investigators and embark on a career path dedicated to clinical research. Additionally, plans for providing mentored Clinical Scholars with opportunities for interdisciplinary interactions and collaborations as part of the training experience should be given.

8. VI. Local Training & Research Resources Available (3 pages maximum). To accomplish the clinical research training goals of the CRCoE, adequate resources must be available for didactic training and research training. Applicants should list and describe the local academic/institutional resources that will be available to the CRCoE for training/coursework in the core disciplines on which clinical research is based. This list may include established Masters-level programs (e.g., Masters of Public Health) at a local university, existing National Institutes of Health K-type awards at the institution, and other resources deemed relevant to providing an academic environment to Clinical Scholars that will ensure their success. If a university partnership is to be fostered to meet training goals, details of the partnership should be given to provide an idea of the nature of partnership and any unique characteristics of the institution (e.g., facilities, opportunities available, etc.) that are conducive to developing Clinical Scholars.

In addition to the academic resources available, describe any local resources such as facilities and/or equipment at the academic institution or local hospital that will be available for clinical research training purposes. It should be clear how any equipment listed will contribute to enhancing the training experience and overall clinical research portfolio of the CRCoE. A brief description of where CRCoE-funded research methodologists will be located (i.e., office space) relative to other key CRCoE activities/personnel should also be given.

Applicants also should specify how the CRCoE will have access to and utilize local academic and clinical resources. Those plans should describe how Clinical Scholars will be able to take the necessary coursework as well as arrangements made in conjunction with the local hospital administration for the time of the Clinical Scholars. If necessary, cooperative agreements for utilizing resources have not been obtained by the time the application is submitted, the specific plans and timelines for obtaining necessary arrangements should be indicated. Access to biostatistical, methodological, and instrument development/evaluation expertise that will serve as core components of the CRCoE also should be discussed.

9. VII. Clinical Research Portfolio (2 page maximum). Describe the existing clinical research portfolio of key CRCoE personnel (e.g., Director, mentors) and how it is directly related to VA patient care. This description should include current funding sources (and amounts) and highlight the strengths of this portfolio in relation to how it can contribute to the clinical research training program of the CRCoE. Any research collaborations that involve an interdisciplinary effort also should be indicated. Furthermore, plans for further maintenance and future development of a dynamic clinical research portfolio may be provided in this section. These plans may include how the CRCoE plans to leverage NIH, industry, or other research funds.

10. VIII. Director & Steering Committee (4 pages maximum). A brief narrative should indicate the qualifications of the proposed CRCoE Director for overseeing and ensuring the success of the CRCoE. This description should include his/her area(s) of clinical and scientific expertise, experience in mentoring and developing young investigators in clinical research, and experience in coordinating training and/or research activities. Key accomplishments and/or awards can be listed to further highlight the proposed Director's commitment to clinical research training.

In addition to the Director, members of the Steering Committee (with current titles/positions) and their explicit roles should be listed. Major roles include coordination of internal activities, evaluation of whether the CRCoE is fulfilling its training and clinical research missions, oversight of Clinical Scholars, and funding administration and management. It should be noted that one of the Steering Committee members is to be a local VAMC administrator who will enable Clinical Scholars to conduct clinical work and also fulfill training goals of this program. Any potentially unique contributions that can be made by key CRCoE staff at the National Planning Meeting of CRCoEs should also be highlighted in this section.

11. IX. Recruitment (1 page maximum). The CRCoE is to be a national resource for training Clinical Scholars and for assisting with the development of clinical research protocols. Describe how the CRCoE will recruit Clinical Scholars to be trained and mentored. This description should also clearly describe efforts for recruiting minorities and underrepresented populations in clinical research and ability of the CRCoE to increase diversity in clinical research within VA.

12. X. Long-term Goals (1 page maximum). Outreach efforts to the clinical research community (local and off-site) should be described and strategic plans for making CRCoE resources available. Describe the anticipated major products and attributes of the program in the long-term. Describe long-term plans for a sustained training program in clinical research and clinical research portfolio.

13. XI. Letters of Endorsement and Support. Include letters of endorsement from the VAMC Director and VISN Director. Include a letter of endorsement from the ACOS R&D and Research and Development Committee. Letters of support from any partnering institution, relevant department chairperson(s), and CRCoE faculty mentors are recommended.

14. Application Submission. The application must be sent through the VAMC Research and Development Office, the Research and Development Committee, the VAMC Director, and other appropriate channels for transmittal to VHA Central Office.

Packages mailed by the U.S. Postal Service should be sent to:

VHA Office of Research and Development (12)
CRCoE Program - Attn: Grant Huang, MPH, Ph.D.
810 Vermont Avenue, NW
Washington, DC 20420

Packages delivered by door-to-door courier services (e.g., FedEx): should be sent to:

VHA Office of Research and Development (12)
Attn: Grant Huang, M.P.H., Ph.D.
1722 I Street, NW
Washington, DC 20006
(202) 254-0252

APPLICATION CHECKLIST

CLINICAL RESEARCH CENTERS OF EXCELLENCE (CRCoEs)

_____1. Front sheet Department of Veterans Affairs (VA) Form 10-1313-1, Merit Review Application, signed by the Associate Chief of Staff Research and Principal Investigator (PI).

_____2. Abstract of the application, i.e., VA Form 10-1313-2, Summary Description of Program.

_____3. Table of Contents with page numbers.

_____4. Narrative Section. A maximum 20 pages containing items I-X.